EXHIBITS 24-26
REDACTED

Exhibit 27

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

2007-1365

ADVANCED CARDIOVASCULAR SYSTEMS, INC.
and GUIDANT SALES CORPORATION,

Plaintiffs-Appellees,

v.

MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,

Defendants-Appellants.

ON MOTION

Before MAYER, GAJARSA, and PROST, Circuit Judges.

PROST, Circuit Judge.

ORDER

Advanced Cardiovascular Systems, Inc. et al. (ACS) move to dismiss Medtronic Vascular, Inc. et al.'s (Medtronic) appeal as premature. Medtronic opposes. ACS replies.

ACS brought suit against Medtronic in the United States District Court for the District of Delaware for patent infringement. Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., No. 98-CV-80 (May 3, 2007). A jury found that Medtronic infringed ACS's patents and that the patents were not invalid. The district court entered "judgment" in favor of ACS, and Medtronic appeals. Pending at the district court are, inter alia, ACS's request for damages and its claim for injunctive relief.

ACS asserts that the appeal is premature because the district court has not yet adjudicated its request for an injunction and thus the district court's "judgment" is not

final except for an accounting pursuant to 28 U.S.C. § 1292(c)(2). ACS cites the Fifth Circuit's decision in Stamicarbon, N.V. v. Escambia Chemical Corp., 430 F.2d 920, 930 (5th Cir. 1970) for the proposition that a case is not final except for an accounting if an unadjudicated request for injunctive relief remains pending before the district court. Medtronic contends that ACS has not yet filed a motion for a permanent injunction and thus the request is not properly before the district court. As such, Medtronic argues that the present appeal is not premature and should not be dismissed.

We agree with ACS that Medtronic's appeal is premature because ACS's request for permanent injunctive relief in its complaint remains pending and thus the case is not final except for an accounting. See PODS, Inc. v. Porta Stor, Inc., 484 F.3d 1359, 1365 (Fed. Cir. 2007) (although appeal was premature under 28 U.S.C. § 1292(c)(2) because request for injunctive relief had not been decided, appeal was treated as timely when district court decided claim for injunctive relief during pendency of appeal); Nystrom v. Trex Co., 339 F.3d 1347, 1350 (Fed. Cir. 2003) ("If a case is not fully adjudicated as to all claims for all parties and there is no express determination that there is no just reason for delay or express direction for entry of judgment as to fewer than all of the parties or claims, there is no final decision under 28 U.S.C. § 1295 (a)(1) and therefore no jurisdiction"). Thus, Medtronic's appeal is premature and must be dismissed.

Accordingly,

IT IS ORDERED THAT:

(1) ACS's motion to dismiss is granted.

(2) Each side shall bear its own costs.

FOR THE COURT

August 1, 2007
Date

/s/ Sharon Prost
Sharon Prost
Circuit Judge

cc: J. Michael Jakes, Esq.
George M. Sirilla, Esq.

s17

ISSUED AS A MANDATE: August 1, 2007

Exhibit 28

Evaluation of the Medtronic (Driver) Cobalt-Chromium Alloy Coronary Stent System

Michael H. Sketch, Jr, MD, Michael Ball, MD, Barry Rutherford, MD, Jeffrey J. Popma, MD, Catherine Russell, RN, BSN, and Dean J. Kereiakes, MD, on behalf of the Driver Investigators

The Driver Registry was a prospective, multicenter, nonrandomized study to evaluate the clinical safety and efficacy of the Driver cobalt-chromium alloy stent. Use of the cobalt-chromium alloy in place of stainless steel offers enhanced visibility and radial strength with thinner structural elements. The registry enrolled 298 patients with symptomatic ischemic heart disease attributable to de novo or restenotic nonstented native lesions of a single vessel amenable to percutaneous stenting. The primary composite end point was the incidence of major adverse cardiac events (death, myocardial infarction, emergency bypass surgery, or target lesion revascularization) 180 days after enrollment. Quantitative coronary angiography was performed before and after the index stent deployment and repeated at 6 months in 83 patients. Mean patient age was 62.6 years, mean reference vessel diameter was 3.07 mm before the procedure, and mean lesion length was 11.04 mm. Fifty-one patients received multiple stents. Angiographic success rate was 100% and procedural success rate was 98.3%. Cumulative incidence of major adverse cardiac events was 5.7% and target lesion revascularization was 3.4% at 180 days. In-stent late loss was 0.94 mm at 180 days, and no subacute stent thromboses were observed. This registry demonstrated the safety and efficacy of this novel coronary stent platform. ©2005 by Excerpta Medica Inc.

(Am J Cardiol 2005;95:8–12)

The Medtronic Driver coronary stent (Medtronic Inc., Minneapolis, Minnesota) is a new low-profile, nonferromagnetic stent with rounded strut edges and a strut thickness of 0.0036 in (Figure 1). Based on the design of the Medtronic S7 stent, the Driver stent is made of a cobalt-chromium based alloy that conforms to the American Society for Testing and Materials F562. This alloy is stronger and denser than 316L stainless steel, allowing for thinner struts, increased flexibility, and better deliverability without compromising radial strength or radiopacity. The Driver Registry was designed to determine the safety and efficacy of the Medtronic Driver stent.

METHODS

This was a prospective, multicenter, nonrandomized study designed to evaluate the safety and efficacy of the Medtronic Driver stent. Patients were enrolled at 23 sites in the United States; a subset of the first 101 patients was scheduled for repeat angiography 180 days after stent implantation. The primary composite end point was the rate of major adverse cardiac events (MACEs)—death, myocardial infarction (Q wave and non–Q wave), emergency coronary artery bypass graft surgery, or target lesion revascularization (TLR)—180 days after the procedure. Secondary end points were acute success; target vessel failure in the hospital and at 14, 30, 180, and 270 days; clinically driven TLR at 180 and 270 days; late loss; angiographic restenosis (≥50% in-stent diameter stenosis at 180 days in the angiographic subset); and ischemic, bleeding, and vascular complications.

Inclusion and exclusion criteria: Study participants were required to have symptomatic ischemic heart disease attributable to stenotic lesions of native coronary arteries that were amenable to percutaneous stenting. Patients with 3-vessel disease were permitted; however, only 1 lesion/patient could be treated in this registry. The target lesion could be de novo or restenotic in native coronary arteries, with a reference vessel diameter of 3.0 to 4.0 mm and length ≤30 mm; restenotic lesions must not have been previously stented or have had any previous treatment other than standard balloon angioplasty.

Procedure: After obtaining vascular access, an introducer sheath of ≥6Fr in size was inserted using the standard approach. After catheter introduction, heparin was administered and supplemented as needed to maintain anticoagulation throughout the procedure. Patients who had received a glycoprotein IIb/IIIa inhibitor had their activated clotting time maintained at >200 seconds; all others had their activated clotting time maintained >250 seconds. After intracoronary injection of nitroglycerin, baseline angiography of the target vessel was performed. The target lesion was pretreated with standard balloon angioplasty. The pro-

From Duke University Medical Center, Durham, North Carolina; St Vincent Hospital/The Heart Center of Indiana, Indianapolis, Indiana; St Luke's Hospital, Kansas City, Missouri; Brigham and Women's Hospital, Boston, Massachusetts; Medtronic Vascular Clinical Research Department, Santa Rosa, California; and Christ Hospital/The Lindner Center for Research and Education/Ohio Heart Health Center, Cincinnati, Ohio. Manuscript received May 6, 2004; revised manuscript received and accepted August 20, 2004

Address for reprints: Michael H. Sketch, Jr., MD, Box 3157, Duke University Medical Center, Durham, North Carolina 27710. E-mail: sketc002@mc.duke.edu

0002-9149/05/$–see front matter
doi:10.1016/j.amjcard.2004.08.055

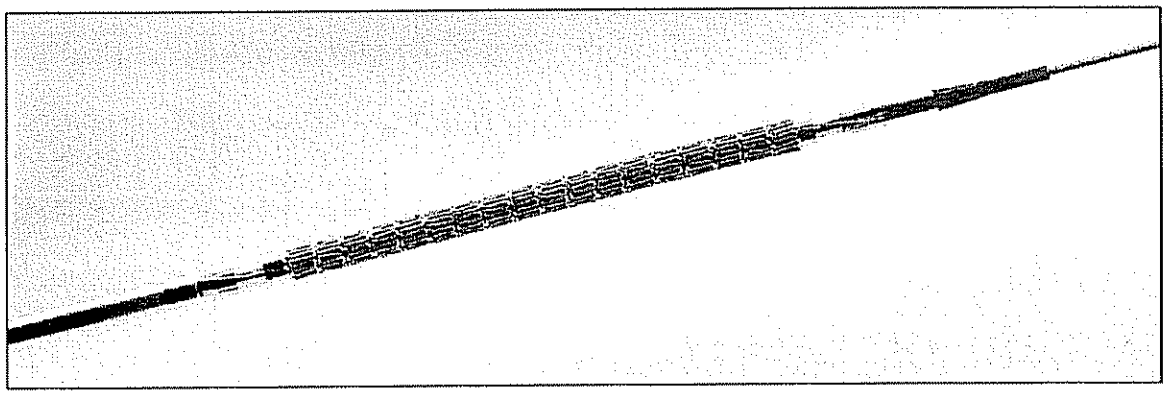

FIGURE 1. The Driver cobalt-chromium alloy coronary stent.

tocol did not allow direct stenting or the use of directional coronary atherectomy, excimer laser, or rotational atherectomy. No more than 2 stents were used (except for a bailout procedure). Immediately after the procedure, heparin was discontinued, and the activated clotting time was monitored in accordance with hospital protocol. Vascular sheaths were removed according to usual hospital practice, and approved vascular closure devices could be used at the discretion of the investigator.

Data collection and analysis: Baseline and follow-up clinical data were collected on case report forms by coordinators at the study sites. Clinical outcomes data were analyzed by an independent clinical research organization (Harvard Clinical Research Institute, Boston, Massachusetts). An independent angiographic core laboratory (Brigham & Women's Hospital Angiographic Core Laboratory) analyzed all baseline and follow-up angiograms to determine lesion success, angiographic adverse events, and thrombolysis in myocardial infarction flow. Angiographic follow-up was performed 180 days after the procedure in a prespecified subset of patients.

Cardiac enzymes (creatine kinase and creatine kinase-MB) were measured at intervals of 6 to 8, 10 to 12, 16 to 18, and 20 to 24 hours after the procedure, and an electrocardiogram was obtained 16 to 24 hours after the procedure or before discharge. Clinical follow-up was performed in the hospital, during office visits at 30 and 180 days after the procedure and via telephone at 14 and 270 days after the procedure. An independent clinical events committee adjudicated all major clinical end points, which were analyzed on an intent-to-treat basis. The primary end point of 180-day MACE was analyzed on an intent-to-treat basis, as were all angiographic end point data for patients assigned to such follow-up.

Definitions: Q-wave myocardial infarction was defined as either (1) the presence of chest pain or other acute symptoms consistent with myocardial ischemia and new pathologic Q waves in ≥2 contiguous electrocardiographic leads, or (2) elevated cardiac enzyme levels >2 times the upper limit of normal associated with any elevation above the upper limit of normal in creatine kinase-MB levels in the presence of new pathologic Q waves. Non–Q-wave myocardial infarction was defined as an elevated creatine kinase ≥2 times the upper limit of normal associated with any elevation above the upper limit of normal in creatine kinase-MB levels in the absence of new pathologic Q waves. TLR was defined as repeat percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery. Target vessel failure was defined as target vessel revascularization, recurrent Q- or non–Q-wave myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel. Acute success was a composite of device, lesion, and procedural successes. Device success was defined as attainment of <50% residual stenosis of the target lesion using only the assigned device, whereas lesion success was defined as attainment of <50% residual stenosis of the target lesion using any percutaneous method. Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE was considered procedural success.

Angiographic analysis: Standard image acquisition was performed at the clinical sites using ≥2 angiographic projections of the stenosis after administration of intracoronary nitroglycerin, and these projections were repeated at the time of follow-up angiography. Angiographic images were recorded on compact disk or cinefilm and forwarded to the Brigham and Women's Hospital Angiographic Core Laboratory for review by observers who were blinded to the clinical outcome. Repeat angiography was planned at 180 ± 30 days in patients assigned to the angiographic subset.

All procedural and follow-up angiograms were reviewed using standard morphologic criteria.[1,2] Lesion length was defined as the axial extent of the lesion that contained a shoulder-to-shoulder lumen reduction of ≥20%. Using the contrast-filled injection catheter as the calibration source, quantitative angiographic analysis was performed using a validated automated edge-detection algorithm (Medis CMS, Leiden, The Netherlands).[3] Selected images were identified using angiographic projections that demonstrated stenosis in an unforeshortened view, minimized the degree of vessel overlap, and displayed the stenosis in its "sharpest and tightest" view. A 5-mm segment of reference diameter proximal and distal to the stenosis was used to calculate the average reference vessel

TABLE 1 Baseline Demographics and Clinical Characteristics of All Treated Patients (n = 298)

Patient Characteristics	
Age (mean ± SD) (yrs)	62.6 ± 10 8
Men	68 1%
Current smoker	28 8%
Prior percutaneous coronary revascularization	23 0%
Hyperlipidemia requiring treatment	75 9%
Diabetes mellitus	27 6%
Hypertension requiring treatment	68 4%
Previous myocardial infarction	28 1%
Premature coronary artery disease in first-degree relative*	49 1%
Prior coronary bypass surgery	6.0%
Canadian Cardiovascular Society angina class III or IV	55 3%
Major coronary stenosis (>50% stenosis)	
1	66 8%
2	22 8%
3	10.4%
Ejection fraction (mean ± SD)	55 9% ± 9 8%
Glycoprotein IIb/IIIa inhibitor usage	32 6%

*First-degree relatives were male relatives <55 years of age and female relatives <65 years of age with premature coronary artery disease.

TABLE 2 Baseline Lesion Characteristics (298 lesions; 292 de novo, 6 restenotic)

Lesion Characteristics	
Preprocedure reference vessel diameter (mm)	3 07 ± 0 47
Preprocedure MLD (mm)	1.01 ± 0.38
Preprocedure percent diameter stenosis	67.1 ± 11.1%
Lesion length (mm)	11 04 ± 4 24
Target vessel	
Left anterior descending	45.1%
Circumflex	19.7%
Right coronary artery	34.5%
Left main coronary artery	0.7%
Calcification (moderate to severe)	14 1%
Thrombus	1 1%
Eccentric lesion	41.2%
Angulation >45°	7 0%
ACC/AHA lesion class	
A	14 8%
B1	34 5%
≥B2	45.1%
C	5.6%

ACC/AHA = American College of Cardiology/American Heart Association.

diameter before and after the index stent procedure and at follow-up. Sidebranches and other anatomic landmarks were used to identify and maintain the consistency of the measurement length during follow-up. Minimal lumen diameter (MLD) was measured at these same time points within the stent (in-stent analysis) and within the segment between the proximal and distal reference that included the 5-mm proximal and distal edges of the stent (in-lesion analysis).

Angiographic follow-up was performed 6 to 9 months after the index procedure, unless earlier angiography was required clinically. Binary angiographic restenosis was defined as the incidence of percent diameter stenosis >50% at the qualifying angiographic follow-up, performed from as early as 1 month for symptomatic patients to up to 9 months for asymptomatic patients. Angiographic percent diameter stenosis was defined as (1 − [MLD/reference vessel diameter]) × 100. Acute gain was defined as the MLD immediately after the procedure minus the MLD before the procedure, and late loss was defined as the MLD immediately after the procedure minus the MLD at 6-month follow-up.

RESULTS

Baseline demographics and lesion characteristics: Among the 298 patients enrolled, baseline demographic and clinical characteristics (Table 1) showed a mean age of 62.6 years; 68.1% were men and 27.6% had a history of diabetes mellitus. Baseline lesion characteristics are listed in Table 2. Mean reference vessel diameter was 3.07 mm, mean preprocedure MLD was 1.01 mm, mean preprocedure percent diameter stenosis was 67.1%, and mean lesion length was 11.04 mm.

Multiple Driver stents were implanted in 17.1% of patients during the index procedure: 49 patients received 2 stents, and 2 patients received 3 stents. Implantation of the additional stents was required to provide adequate lesion coverage. In 98% of these patients, total stent lengths was >18 mm (range 21 to 42).

Acute clinical outcomes: Table 3 presents the safety and efficacy results. The device and lesion success rates were 100%. The procedural success rate was 98.3%; 5 procedures were considered unsuccessful because of the occurrence of a non–Q-wave myocardial infarction on the day of the procedure. These 5 cases accounted for the 1.7% in-hospital incidence of MACE.

In 284 patients for whom data were available, the postprocedure in-lesion MLD was 2.55 ± 0.50 mm, with a postprocedure in-lesion percent diameter stenosis of 15.0%. The postprocedure in-stent MLD was 2.90 ± 0.41 mm, with a postprocedure in-stent percent diameter stenosis of 3.0%.

Long-term (180- and 270-day) clinical outcomes: The incidence of MACEs at 180 days—the primary end point of this study—was 5.7%. By 180 days, 10 of the 298 patients (3.4%) required TLR; 8 (2.7%) underwent percutaneous transluminal coronary angioplasty, and 2 (0.7%) underwent coronary artery bypass graft surgery. By 270 days, an additional 11 patients (3.7%) had undergone percutaneous transluminal coronary angioplasty, for an overall TLR rate of 7.0%.

The 270-day Kaplan-Meier estimate of freedom from TLR was 91.2% (95% confidence interval 86.5% to 95.8%), from target vessel revascularization 90.0% (95% confidence interval 85.1% to 95.0%), from target vessel failure 88.3% (95% confidence interval 83.1% to 93.6%), and from MACE 87.7% (95% confidence interval 82.4% to 93.1%).

Clinical events reported between hospital discharge and the 270-day follow-up included 4 noncardiac deaths (1.3%), 1 cerebrovascular accident (0.3%), and 1 bleeding complication (0.3%). A total of 7

TABLE 3 Acute and Long-term Clinical and Angiographic Outcomes (n = 298)

Efficacy Measures	Outcome	
Acute success		
Device	100 0%	
Lesion	100 0%	
Procedural	98 3%	
Postprocedure lesion characteristics		
Reference vessel diameter (mm)	3 01 ± 0 48	
MLD (mm)		
In stent	2 90 ± 0 41	
In lesion	2 55 ± 0 50	
Percent diameter stenosis		
In-stent	3 0 ± 10 5	
In-lesion	15 0 ± 11 4	
In-hospital complications		
MACEs	1 7%	
Out-of-hospital complications	At 180 d	At 270 d
MACEs	4 0%	8 4%
TLR	3 4%	7 0%
Target vessel revascularization	4 4%	8 1%
Target vessel failure	5 0%	8 1%
Angiographic results at 180 d		
Binary restenosis		
In-stent	15 7% (13/83)	
In-lesion	15 7% (13/83)	
In-stent late loss (mm)	0 94 ± 0 54	
In-lesion late loss (mm)	0 62 ± 0 56	

bleeding complications (2.3%) occurred. These included 1 surgical repair of a vascular complication related to the index procedure 3 days after the procedure and 6 transfusions during the index hospitalization. During the follow-up, 2 patients (0.7%) experienced vascular complications. Overall, including both the in-hospital and out-of-hospital events, 10 of 298 patients (3.4%) experienced a total of 12 vascular complications: 5 pseudoaneurysms, 1 arteriovenous fistula, 5 hematomas >5 cm in diameter, and 1 incident of peripheral ischemia that was repaired surgically. Two of these patients had multiple vascular complications; 1 patient had a non–Q-wave myocardial infarction and a bleeding complication, and 1 had a non–Q-wave myocardial infarction and a vascular complication. No incidents of stent thrombosis, subacute closure, or abrupt closure were reported during the 270-day follow-up period.

Clinical outcomes with respect to the occurrence of MACEs, target vessel revascularization, stent thrombosis, major vascular complications, cerebrovascular accidents, perforations, or major bleeding complications were similar in patients who received total implanted stent lengths ≤18 mm (n = 248) and in patients who had multiple stents with a total length of >18 mm (n = 50).

Angiographic outcomes at 180 days: Of the 83 evaluable patients in the angiographic subset (the first 101 patients enrolled in the registry) who returned for protocol-specified angiography at 180 days after the procedure, 15.7% had binary angiographic restenosis, defined as ≥50% in-stent diameter stenosis (Table 3). Mean in-stent late loss at 180 days in 82 of these patients (baseline angiographic data were missing for 1 patient) was 0.94 mm.

DISCUSSION

In this prospective, multicenter, nonrandomized study, deployment of the thin-strut Medtronic Driver stent was safe (1.7% non–Q wave infarction) and effective both early (lesion and device success 100%) and late (6-month postdischarge MACEs 4.0%, clinically-driven TLR 3.4%, and binary angiographic restenosis 15.7%). The procedure success rate was 98.3% as a result of 5 implantations (1.7%) associated with a non–Q-wave infarction on the day of the procedure. The cumulative incidence of MACEs to 6 months after implantation (5.7%) in the 269 patients (90.3%) available for clinical follow-up compares favorably with that previously observed after deployment of the Wiktor (Medtronic Inc.), NIR (Medinal Ltd, Tel Aviv, Israel), Bard XT (Bard Ireland Ltd., Galway, Ireland), or Tenax (Biotronik BmbH, Berlin, Germany) stents (10.4%)[9] as well as the S670 stent (13.5%)[4,5]

After Driver stent implantation, the incidence of clinically driven TLR to 6 months was low (3.4%) compared with that reported from a meta-analysis of 10 stent trials (10.0%)[6] and the previously mentioned study of the Wiktor, NIR, Bard XT, and Tenax stents (6.1% at 6 months).[4] Multivariable analysis in this study of these 4 stents revealed that the MLD after the procedure and stent type were the only independent predictors of 24-month TLR.[9] The relation between clinical or angiographic restenosis and stent design may reflect the degree of vessel injury during stent deployment and consequent differences in the neointimal proliferative response.[7–10]

The incidence of binary (>50%) in-stent restenosis (15.7%) in the subset of 83 patients at 180 days was similar to rates observed in both the Intracoronary Stenting And Angiographic Results: Strut Thickness Effect on REstenosis Outcome (ISAR-STEREO-1) and ISAR-STEREO-2 trials after deployment of another thin-strut stent (Multi-Link, Guidant Vascular Interventional Group, Santa Clara, California)) design (15% and 17.9%, respectively).[11,12] In a recent comparative study of 5 stainless steel coronary stent designs (InFlow, Inflow Dynamics AG, Munich, Germany; Multi-Link, NIR, Palmaz-Schatz, Cordis, Miami Lakes, Florida; and PURA-A, Devon Medical, Hamburg, Germany) in 1,147 patients, which included angiographic follow-up at 6 months, binary restenosis rates ranged from 25.3% to 35.9%. In an additional large series of patients with follow-up angiography after 6 months, binary restenosis ranged from 20.0% to 50.3%. In both of these comparative studies, stent design and reference vessel diameters were the strongest predictors of restenosis by logistic regression.[13,14]

In addition to stent design and small reference vessel diameter, longer stent length[10,15,16] and diabetes mellitus[4,10,15] have been identified as independent predictors of late (≥6 months) restenosis and TLR. In the Driver Registry, no significant differences in clinical outcomes were observed 6 months after intervention among patients who had single versus multiple stents deployed and a total stent length of ≤18 mm (n = 248) versus patients who had multiple stents im-

TABLE 4 Comparison of Clinical and Angiographic Outcomes With Cobalt-chromium Alloy Stents

	MedIronic Driver Stent	Guidant Multi-Link Vision Stent
No. of patients	298	267
Procedural success	98.3%	99.0%
MACEs at 180 d	5.7%	6.2%
Target vessel failure up to 180 d	5.0%	6.7%
Binary in-stent restenosis	15.7%	15.7%
In-stent late loss	0.94 ± 0.54%	0.83 ± 0.56%

MACEs were defined as death, Q-wave and non–Q-wave myocardial infarction, emergency coronary artery bypass graft surgery, or TLR.

planted with a combined total stent length of >18 mm (n = 50). No differences were observed between diabetic (n = 82) and nondiabetic (n = 215) patients.

In a recent meta-analysis of multiple clinical trials in which patients had stents deployed for de novo or restenotic native coronary artery lesions and were followed for >6 months, the incidence of clinical restenosis and need for revascularization increased with the duration of follow-up.[17] At 6-month follow-up, TLR, target vessel revascularization, and target vessel failure were observed in 6.9%, 8.0%, and 9.6% of patients, respectively, whereas at 9 months these rates increased to 10.2%, 12.1%, and 13.6%, respectively. Comparable rates in the Driver Registry were 3.4%, 4.4%, and 6.7% at 6 months, and 7.0%, 8.1%, and 9.7% at 9 months, respectively.

The only other cobalt-chromium alloy stent to have undergone clinical evaluation is the Guidant Multi-Link Vision stent, which is also a thin (0.0032-in) strut design. The clinical and angiographic outcomes observed after Driver stent deployment compare favorably with the outcomes reported from the Guidant Multi-Link Vision stent registry (Table 4).[18]

1. Ellis S, Vandormael M, Cowley M, DiSciascio G, Deligonul U, Topol EJ, Bulle TM. Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel coronary disease. *Circulation* 1990;82:1193–1202.

2. Ryan T, Faxon D, Gunnar R, Kennedy JW, King SB, III, Loop FD, Peterson KL, Reeves TJ, Williams DO, Winters WL, Jr, et al. Guidelines for percutaneous transluminal coronary angioplasty: a report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Percutaneous Transluminal Coronary Angioplasty). *J Am Coll Cardiol* 1988;12:529–545.

3. van der Zwet PM, Reiber JH. A new approach for the quantification of complex lesion morphology: the gradient field transform: basic principles and validation results. *J Am Coll Cardiol* 1994;24:216–224.

4. Elbaz M, El Mokhtar E, Fourcade J, Mourali S, Hobeika R, Carrié D, Puel J. Does stent design affect the long-term outcome after coronary stenting? *Catheter Cardiovasc Interventions* 2002;56:305–311.

5. Legrand VM, Garcia EJ, Grube E, Khalife K, Bonnier H, Commeau P, Przewlocki T, Macaya C, Witkowski A, on behalf of the Race Car Study Investigators. Clinical and angiographic performance of a new-generation modular stent design for treatment of de novo coronary lesions. *Catheter Cardiovasc Interventions* 2001;54:276–282.

6. Burzotta F, Trani C, Prati F, Hamon M, Mazzari MA, Mongiardo R, Sabatier R, Boccanelli A, Schiavoni G, Crea F. Comparison of outcomes (early and six-month) of direct stenting with conventional stenting (a meta-analysis of ten randomized trials). *Am J Cardiol* 2003;91:790–796.

7. Hoffmann R, Jansen C, König A, Haager PK, Kerckhoff G, vom Dahl J, Klauss V, Hanrath P, Mudra H. Stent design related neointimal tissue proliferation in human coronary arteries: an intravascular ultrasound study. *Eur Heart J* 2001;22:2007–2014.

8. Farb A, Weber DK, Kolodgie FD, Burke AP, Virmani R. Morphological predictors of restenosis after coronary stenting in humans. *Circulation* 2002;105:2974–2980.

9. König A, Schiele TM, Rieber J, Theisen K, Mudra H, Klauss V. Influence of stent design and deployment technique on neointima formation and vascular remodeling. *Z Kardiol* 2002;91(suppl 3):98–102.

10. Kereiakes D, Linnemeier TJ, Baim DS, Kuntz R, O'Shaughnessy C, Hermiller J, Fink S, Lansky A, Nishimura N, Broderick TM, Popma J. Usefulness of stent length in predicting in-stent restenosis (the MULTI-LINK stent trials). *Am J Cardiol* 2000;86:336–341.

11. Kastrati A, Mehilli J, Dirschinger J, Dotzer F, Schühlen H, Neumann F-J, Fleckenstein M, Pfafferott C, Seyfarth M, Schömig A. Intracoronary Stenting and Angiographic Results: Strut Thickness Effect on Restenosis Outcome (ISAR-STEREO) trial. *Circulation* 2001;103:2816–2821.

12. Pache J, Kastrati A, Mehilli J, Schühlen H, Dotzer F, Hausleiter J, Fleckenstein M, Neumann F-J, Sattelberger U, Schmitt C, et al. Intracoronary Stenting and Angiographic Results: Strut Thickness Effect on Restenosis Outcome (ISAR-STEREO-2) trial. *J Am Coll Cardiol* 2003;41:1289–1292.

13. Kastrati A, Dirschinger J, Boekstegers P, Elezi S, Schühlen H, Pache J, Steinbeck G, Schmitt C, Ulm K, Neumann F-J, Schömig A. Influence of stent design on 1-year outcome after coronary stent placement: a randomized comparison of five stent types in 1,147 unselected patients. *Catheter Cardiovasc Interventions* 2000;50:290–297.

14. Kastrati A, Mehilli J, Dirschinger J, Pache J, Ulm K, Schühlen H, Seyfarth M, Schmitt C, Blasini R, Neumann F-J, Schömig A. Restenosis after coronary placement of various stent types. *Am J Cardiol* 2001;87:34–39.

15. Briguori C, Sarais C, Pagnotta P, Liistro F, Montorfano M, Chieffo A, Sgura F, Corvaja N, Albiero R, Stankovic G, et al. In-stent restenosis in small coronary arteries: impact of strut thickness. *J Am Coll Cardiol* 2002;40:403–409.

16. Goldberg SL, Loussararian A, De Gregorio J, Di Mario C, Albiero R, Colombo A. Predictors of diffuse and aggressive intra-stent restenosis. *J Am Coll Cardiol* 2001;37:1019–1025.

17. Cutlip DE, Chauhan MS, Baim DS, Ho KK, Popma JJ, Carrozza JP, Cohen DJ, Kuntz RE. Clinical restenosis after coronary stenting: perspectives from multicenter clinical trials. *J Am Coll Cardiol* 2002;40:2082–2089.

18. Kereiakes DJ, Cox DA, Hermiller JB, Midei MG, Bachinsky WB, Nukta Ed, Leon MB, Fink S, Marin L, Lansky AJ, for the Guidant Multi-Link Vision Stent Registry Investigators. Usefulness of a cobalt chromium coronary stent alloy. *Am J Cardiol* 2003;92:463–466.

EXHIBITS 29
REDACTED